

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KALEO, INC.,)
)
Plaintiff,)
)
v.) C.A. No. _____
)
ADAMIS PHARMACEUTICALS CORP.,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff kaleo, Inc. (“kaleo”) for its complaint against defendant, Adamis Pharmaceuticals Corp. (“Adamis”), and to the best of its knowledge, information and belief, alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code. This action arises from Adamis’s submission of New Drug Application (“NDA”) No. 212854 to the United States Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a naloxone HCl injector product prior to the expiration of United States Patent No. 9,022,022 (“the ‘022 Patent”) (attached as Exhibit A), United States Patent No. 10,143,792 (“the ‘792 Patent”) (attached as Exhibit B), and/or United States Patent No. 10,238,806 (“the ‘806 Patent”) (attached as Exhibit C), (collectively “Patents-in-Suit”).

THE PARTIES

2. kaleo is a corporation organized and existing under the laws of the State of Virginia, with a principal place of business at 111 Virginia Street, Suite 300, Richmond, Virginia, 23219. kaleo is a pharmaceutical company dedicated to developing innovative solutions for serious and life-threatening medical conditions.

3. kaleo is the holder of approved New Drug Application Nos. 209862 (“kaleo’s NDA”) and 205787. Pursuant to this NDA, kaleo developed, manufactures, and markets its naloxone HCl auto injector product under the proprietary name EVZIO® auto-injector. The EVZIO® product is an easy to use auto-injector prescription product for use in adults and children for the treatment of an opioid emergency such as an overdose or a possible opioid overdose.

4. In connection with kaleo’s NDA, kaleo submitted information concerning the ‘022 Patent for listing in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as required by the Federal Food, Drug, and Cosmetic Act (“FDCA”) and FDA regulations.

5. In connection with kaleo’s NDA, kaleo intended to submit information concerning the ‘792 Patent for listing in the Orange Book as required by the FDCA on January 2, 2019, however, a typographical error resulted in the wrong patent number being listed. kaleo has since corrected the typographical error. The ‘792 Patent is listed in the Orange Book.

6. Adamis is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 11682 El Camino Real, Suite 300, San Diego, California, 92130.

7. On information and belief, Adamis manufactures, sells, markets, and distributes pharmaceutical products throughout the United States, including in this district.

8. On information and belief, Adamis developed its proposed Naloxone Hydrochloride (5mg/0.5mL) injection drug product (“the Adamis NDA Product”) and prepared NDA No. 212854 for submission to the FDA. On information and belief, upon receiving approval of its NDA No. 212854, Adamis will manufacture, sell, offer to sell, and/or import the Adamis NDA Product in the United States, including in this district.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act. Based on the facts alleged herein, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

10. Adamis has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) by submitting NDA No. 212854 seeking FDA approval to manufacture, use, sell, and offer for sale the Adamis NDA Product prior to the expiration of the Patents-in-Suit.

11. On information and belief, Adamis sought FDA approval because it intends to commit acts of patent infringement under 35 U.S.C. § 271(a), (b), and (c) through its manufacture, use, sale, and offer for sale of the Adamis NDA Product throughout the United States.

12. An actual and justiciable controversy exists between the parties under the patent laws of the United States, Title 35 of the United States Code.

13. By letter dated April 3, 2019, Adamis provided kaleo with notice pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) stating its intention to “engage in the commercial manufacture, use, sale, of [the Adamis NDA Product] before the expiration of Orange Book listed United States patents” including the ‘022 Patent. kaleo is bringing this action within 45-days of its receipt of that notice.

14. The Court has personal jurisdiction over Adamis because Adamis is a corporation organized under the laws of the State of Delaware and is registered to do business in the State of Delaware under Business ID Number 82-0429727.

15. On information and belief, this Court also has personal jurisdiction over Adamis because Adamis has at all relevant times maintained continuous and systematic contacts with the State of Delaware, including but not limited to, preparing pharmaceuticals that Adamis distributes throughout the United States.

16. On information and belief, the Adamis NDA Product will be marketed and distributed in Delaware by Adamis, prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state. Thus, on information and belief Adamis will place products that will infringe the Patents-in-Suit into the stream of commerce with the reasonable expectation that actual or potential users of such products are located within this judicial district.

17. Venue is proper in this district under 28 U.S.C. § 1400(b) because Adamis is incorporated in Delaware.

BACKGROUND

kaleo's EVZIO® Product

18. On April 3, 2014, the FDA approved kaleo's NDA for EVZIO® (naloxone HCl injection) auto-injector, 0.4 mg, NDA No. 205787. kaleo began marketing the EVZIO® auto-injector shortly after that approval. On October 19, 2016, the FDA approved kaleo's NDA for EVZIO® (naloxone HCl injection) auto-injector, 2 mg, NDA No. 209862.

19. EVZIO® is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, and for immediate administration as emergency therapy in settings where opioids may be present.

kaleo's Patents

20. The United States Patent & Trademark Office (“USPTO”) duly and legally issued the ‘022 Patent, titled “Medicament Delivery Device for Administration of Opioid Antagonists Including Formulations for Naloxone” on May 5, 2015.

21. kaleo is the owner by assignment of the ‘022 Patent, which lists Eric S. Edwards, Evan T. Edwards, Mark J. Licata and Frank E. Blondino as its inventors. The ‘022 Patent claims a medicament delivery device for administration of opioid antagonists.

22. The USPTO duly and legally issued the ‘792 Patent, titled “Medicament Delivery Device for Administration of Opioid Antagonists Including Formulations for Naloxone” on December 4, 2018.

23. kaleo is the owner by assignment of the ‘792 Patent, which lists Eric S. Edwards, Evan T. Edwards, Mark J. Licata and Frank E. Blondino as its inventors. The ‘792 Patent claims methods of administration of opioid antagonists using a medicament delivery device.

24. The USPTO duly and legally issued the ‘806 Patent, titled “Medicament Delivery Devices for Administration of a Medicament Within a Prefilled Syringe” on March 6, 2019.

25. kaleo is the owner by assignment of the ‘806 Patent, which lists Eric S. Edwards, Evan T. Edwards, Mark J. Licata and Paul F. Meyers as its inventors. The ‘806 Patent claims a medicament delivery device for administration of medicament, including naloxone, using a prefilled syringe.

COUNT I
(Infringement of the ‘022 Patent Under 35 U.S.C. § 271(e)(2)(A))

26. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

27. Adamis submitted NDA No. 212854 to the FDA under section 505(b)(2) of the FDCA seeking to obtain approval to engage in the manufacture, use or sale throughout the

United States, of the Adamis NDA Product prior to the expiration of the ‘022 Patent. By submitting NDA No. 212854, Adamis has committed an act of infringement of one or more claims of the ‘022 Patent under 35 U.S.C. § 271(e)(2)(A).

28. The commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product prior to the expiration of the ‘022 Patent would infringe the ‘022 Patent.

29. On information and belief, Adamis knows of the ‘022 Patent and knows that its commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product will actively induce and contribute to the infringement of the ‘022 Patent.

30. On information and belief, Adamis knows that the Adamis NDA Product will be especially made for or especially adapted for use in infringement of the ‘022 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product will actively contribute to the infringement of the ‘022 Patent.

COUNT II
(Declaratory Judgment of Infringement of the ‘022 Patent Under 35 U.S.C. § 271(a))

31. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

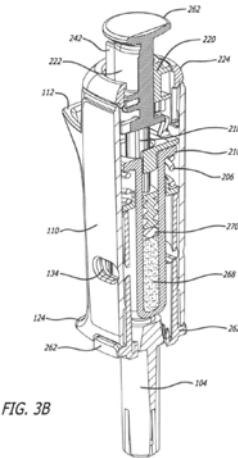
32. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

33. An actual case or controversy between kaleo and Adamis exists such that the Court may entertain kaleo’s request for declaratory relief consistent with Article III of the United States Constitution.

34. Adamis has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import the Adamis NDA Product.

35. Any commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product prior to the expiration of the ‘022 Patent will infringe at least claims 18 and 19 of the ‘022 Patent either literally or under the doctrine of equivalents.

36. For example, claim 18 of the ‘022 Patent recites an apparatus, comprising a housing. the Adamis NDA Product apparatus includes a housing.

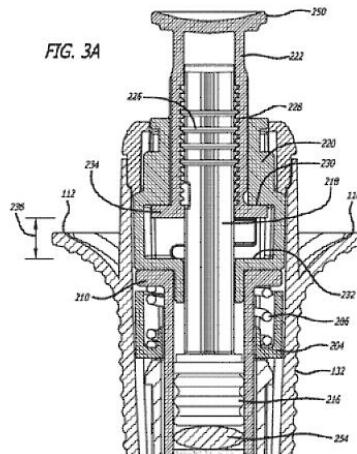


38. Claim 18 of the ‘022 Patent recites an apparatus comprising a medicament container assembly including a naloxone composition including a tonicity-adjusting agent and a pH adjusting agent. On information and belief, the Adamis NDA Product includes a medicament container assembly including a naloxone composition including a tonicity-adjusting agent and a pH adjusting agent.

39. Claim 18 of the ‘022 Patent recites that the pH of the naloxone composition ranges from about 3-5. On information and belief, the Adamis NDA Product includes a naloxone composition with a pH in the range of 3-5.

40. Claim 18 of the ‘022 Patent recites a silicone-based material such that the medicament container assembly is compatible with the naloxone composition. On information and belief, the Adamis NDA Product includes a silicone-based material.

41. Claim 18 of the ‘022 Patent recites an apparatus comprising a plunger. The Adamis NDA product includes a plunger 218.



assembly when the actuator is moved relative to the housing. The Adamis NDA Product includes an actuator 222 configured to cause a force to be exerted on the plunger to expel the naloxone composition from the medicament container assembly when the actuator is moved relative to the housing.

44. kaleo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product by Adamis prior to the expiration of the ‘022 Patent will infringe that patent.

45. On information and belief, despite having actual notice of the ‘022 Patent, Adamis continues to prepare to infringe the ‘022 Patent in disregard of kaleo’s rights, making this case exceptional and entitling kaleo to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT III
**(Declaratory Judgment of Infringement of the ‘022 Patent Under
35 U.S.C. § 271(b) and (c))**

46. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

47. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. An actual case or controversy between kaleo and Adamis exists such that the Court may entertain kaleo’s request for declaratory relief consistent with Article III of the United States Constitution.

49. On information and belief, Adamis has acted with full knowledge of the ‘022 Patent and without a reasonable basis for believing that Adamis would not be liable for actively inducing or contributing to the infringement of the ‘022 Patent.

50. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product would induce the infringement of the ‘022 Patent.

51. On information and belief, Adamis knows that its commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product would actively induce the infringement of the ‘022 Patent.

52. Adamis’s acts of infringement will be done with knowledge of the ‘022 Patent and with the intent to encourage infringement.

53. On information and belief, Adamis knows that the Adamis NDA Product will be especially made or especially adapted for use in an infringement of the ‘022 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

54. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product will contribute to the infringement of the ‘022 Patent.

55. On information and belief, Adamis knows that Adamis’s offer for sale, sale and/or importation of the Adamis NDA Product would contribute to the infringement of the ‘022 Patent.

56. kaleo is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product would induce and/or contribute to infringement of the ‘022 Patent.

57. Unless Adamis is enjoined from actively inducing and contributing to the infringement of the ‘022 Patent, kaleo will suffer irreparable injury for which damages are not an adequate remedy.

58. On information and belief, despite having actual notice of the ‘022 Patent, Adamis is preparing to actively induce and/or contribute to infringement of the ‘022 Patent in

disregard of kaleo's rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV
(Infringement of the '792 Patent Under 35 U.S.C. § 271(e)(2))

59. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

60. Adamis submitted ANDA No. 212854 to the FDA under section 505(b)(2) of the FDCA seeking to obtain approval to engage in the manufacture, use or sale throughout the United States, of the Adamis NDA Product prior to the expiration of the '792 Patent. By submitting ANDA No. 212854, Adamis has committed an act of infringement of the '792 Patent under 35 U.S.C. § 271(e)(2).

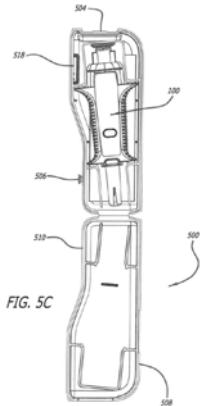
61. The commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product prior to the expiration of the '792 Patent would infringe the '792 Patent.

62. On information and belief, Adamis knows of the '792 Patent and knows that its commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product would actively induce and contribute to the infringement of the '792 Patent.

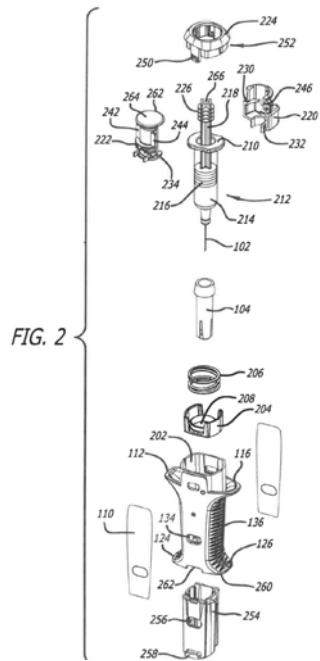
63. On information and belief, Adamis knows or is willfully blind to the fact that the Adamis NDA Product will be especially made for or especially adapted for use in infringement of the '792 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product will actively contribute to the infringement of the '792 Patent.

COUNT V
**(Declaratory Judgment of Infringement of the ‘792 Patent Under
35 U.S.C. § 271(b) and (c))**

64. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.
65. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
66. An actual case or controversy between kaleo and Adamis exists such that the Court may entertain kaleo’s request for declaratory relief consistent with Article III of the United States Constitution.
67. On information and belief, Adamis has acted with full knowledge of the ‘792 Patent and without a reasonable basis for believing that Adamis would not be liable for actively inducing or contributing to the infringement of the ‘792 Patent.
68. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product would induce the infringement of at least claims 16-26 of the ‘792 Patent either literally or under the doctrine of equivalents.
69. For example, claim 16 of the ‘792 Patent recites a method of delivering a single dose of a naloxone composition to a patient. On information and belief, the Adamis NDA Product delivers a single dose of naloxone to a patient.
70. Claim 16 of the ‘792 Patent recites a method of delivering a single dose of a naloxone composition to a patient comprising removing a medical injector containing the naloxone composition from a case. Use of the Adamis NDA Product includes removing a medical injector containing the naloxone composition from a case 500.

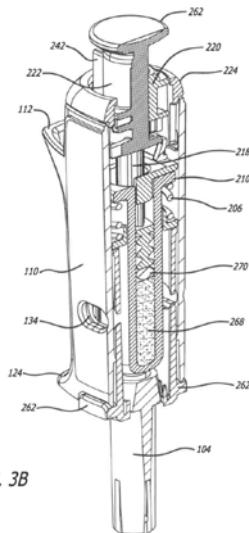


71. Claim 16 of the '792 Patent recites a medical injector including a housing, a prefilled medicament container assembly, and a needle. The Adamis NDA Product includes a housing, prefilled medicament container assembly, e.g., 212 and a needle 102.

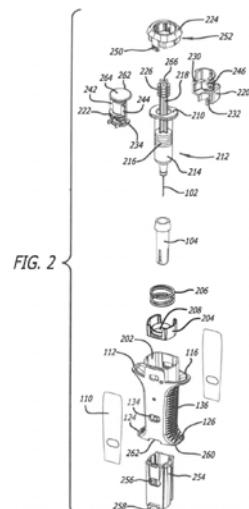


72. Claim 16 of the '792 Patent recites a prefilled medicament container assembly disposed within the housing and including a container body. The Adamis NDA Product includes a prefilled medicament container assembly 212 disposed within the housing and includes a container body that defines an internal volume 214.

73. Claim 16 of the ‘792 Patent recites that the naloxone composition is contained within the container body. In the Adamis NDA Product, the naloxone composition 268 is contained within the container body internal volume 214.



74. Claim 16 of the ‘792 Patent recites an elastomeric member that seals the naloxone composition within the container body. The Adamis NDA Product includes an elastomeric member 216 that seals the naloxone composition within the container body.



75. Claim 16 of the ‘792 Patent recites that the naloxone composition includes a tonicity-adjusting agent and a pH adjusting agent. On information and belief, the Adamis NDA

Product includes a naloxone composition including a tonicity-adjusting agent and a pH adjusting agent.

76. Claim 16 of the ‘792 Patent recites that the pH of the naloxone composition ranges from 3-5. On information and belief, the Adamis NDA Product includes a naloxone composition with a pH ranging from 3-5.

77. Claim 16 of the ‘792 Patent recites a needle coupled to the prefilled medicament container assembly before the removing. On information and belief, the Adamis NDA Product includes a needle coupled to the prefilled medicament container assembly before the medical injector is removed from the case.

78. Claim 16 of the ‘792 Patent recites receiving an instruction associated with a use of the medical injector. Use of the Adamis NDA Product includes receiving instructions associated with its use. For example, the Adamis NDA Product includes visual instructions on the device.

79. Claim 16 of the ‘792 Patent recites placing a portion of the medical injector into contact with the patient. On information and belief, use of the Adamis NDA Product includes placing a portion of the medical injector into contact with the patient.

80. Claim 16 of the ‘792 Patent recites actuating the medical injector to cause the elastomeric member to move within the container body to convey the single dose of the naloxone composition from the container body via the needle. On information and belief, the Adamis NDA Product includes manually actuating the medical injector to cause the elastomeric member to move within the container body to convey the single dose of the naloxone composition from the container body via the needle.

81. On information and belief, Adamis knows or is willfully blind to the fact that its commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product will actively induce the infringement of the ‘792 Patent.

82. On information and belief, Adamis will encourage another’s infringement of the ‘792 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product, the use of which is covered by the claims of the ‘792 Patent.

83. Adamis’s acts of infringement will be done with knowledge of the ‘792 Patent and with the intent to encourage infringement.

84. On information and belief, Adamis knows or is willfully blind to the fact that the Adamis NDA Product will be especially made or especially adapted for use in infringement of the ‘792 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

85. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product will contribute to the infringement of the ‘792 Patent.

86. On information and belief, Adamis knows or is willfully blind to the fact that Adamis’s offer for sale, sale and/or importation of the Adamis NDA Product will contribute to the infringement of the ‘792 Patent.

87. kaleo is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product would induce and/or contribute to infringement of the ‘792 Patent.

88. Unless Adamis is enjoined from actively inducing and contributing to the infringement of the ‘792 Patent, kaleo will suffer irreparable injury for which damages are not an adequate remedy.

89. On information and belief, despite having actual notice of the ‘792 Patent, Adamis is preparing to actively induce and contribute to infringement of the ‘792 Patent in disregard of kaleo’s rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT VI
(Infringement of the ‘806 patent under 35 U.S.C. § 271(e)(2))

90. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

91. Adamis submitted ANDA No. 212854 to the FDA under section 505(b)(2) of the FDCA seeking to obtain approval to engage in the manufacture, use or sale throughout the United States, of the Adamis NDA Product prior to the expiration of the ‘806 Patent. By submitting ANDA No. 212854, Adamis has committed an act of infringement of the ‘806 Patent under 35 U.S.C. § 271(e)(2).

92. The commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product prior to the expiration of the ‘806 Patent would infringe the ‘806 Patent.

93. On information and belief, Adamis knows of the ‘806 Patent and knows that its commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product would actively induce and contribute to the infringement of the ‘806 Patent.

94. On information and belief, Adamis knows or is willfully blind to the fact that the Adamis NDA Product will be especially made for or especially adapted for use in infringement of the ‘806 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or

importation of the Adamis NDA Product will actively contribute to the infringement of the ‘806 patent.

COUNT VII

(Declaratory Judgment of Infringement of the ‘806 Patent Under 35 U.S.C. § 271(a))

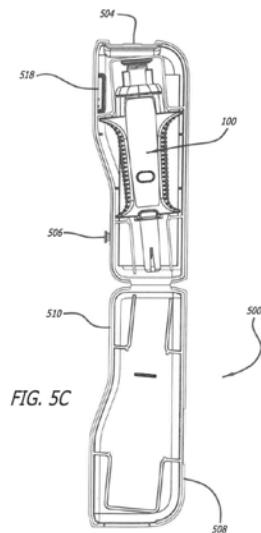
95. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

96. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual case or controversy between kaleo and Adamis exists such that the Court may entertain kaleo’s request for declaratory relief consistent with Article III of the United States Constitution.

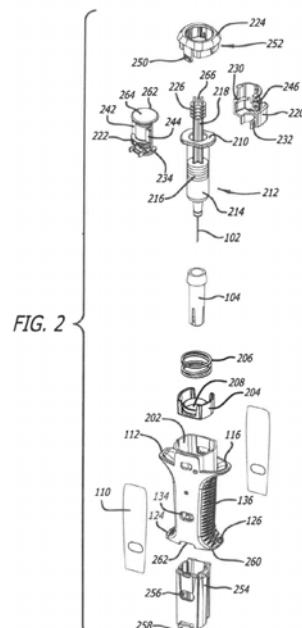
97. Adamis has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import the Adamis NDA Product.

98. Any commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product prior to the expiration of the ‘806 Patent would infringe at least claims 1-3, 6-9 and 12-13 of the ‘806 Patent either literally or under the doctrine of equivalents.

99. For example, claim 1 of the ‘806 Patent recites an apparatus comprising a cover member. The Adamis NDA Product includes a cover member 500.



100. Claim 1 of the ‘806 Patent recites a prefilled syringe assembly including a syringe body, an elastomeric member disposed within the syringe body, and a needle staked to a distal end portion of the syringe body. The Adamis NDA Product includes a prefilled syringe assembly 212 including a syringe body that defines a volume 214, an elastomeric member 216 disposed within the syringe body, and a needle 102 staked to a distal end portion of the syringe body.



101. Claim 1 of the ‘806 Patent recites a proximal end portion of the syringe body including a flange. The Adamis NDA Product includes a proximal end portion of the syringe body including a flange 210.

102. Claim 1 of the ‘806 Patent recites a piston member having a distal end configured to move within the syringe body between a first position and a second position to convey a dose of a medicament from the syringe body through the needle during an injection event. On information and belief, the Adamis NDA Product includes a piston member 218 having a distal end configured to move within the syringe body between a first position and a second position to

convey a dose of a medicament from the syringe body through the needle during an injection event.

103. Claim 1 of the ‘806 Patent recites a syringe enclosure removably disposed within the cover member. The Adamis NDA Product includes a syringe enclosure (e.g., the device outer casing) removably disposed within the cover member 500.

104. Claim 1 of the ‘806 Patent recites a syringe enclosure defining an internal volume within which the proximal end portion of the syringe body is disposed before and during the injection event. The Adamis NDA Product includes a syringe enclosure defining an internal volume within which the proximal end portion of the syringe body is disposed before and during the injection event.

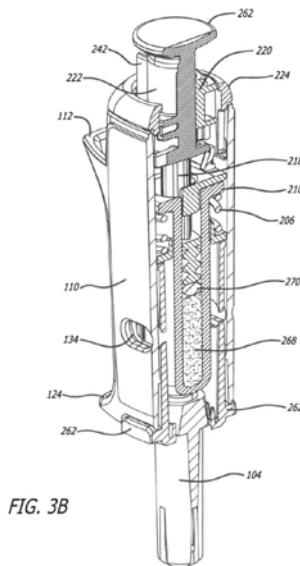
105. Claim 1 of the ‘806 Patent recites the medicament within the syringe body being visible through the syringe enclosure when the syringe enclosure is removed from the cover member. The Adamis NDA Product includes the medicament within the syringe body that is visible through an opening in the syringe enclosure when the syringe enclosure is removed from the cover member (i.e., case 500).

106. Claim 1 of the ‘806 Patent recites the cover member obstructing the view of the medicament within the syringe body when the syringe enclosure is within the cover member. On information and belief, the Adamis NDA Product includes a cover member (i.e., case 500) obstructing the view of the medicament within the syringe body when the syringe enclosure is within the cover member.

107. Claim 1 of the ‘806 Patent recites a distal end of the needle extending beyond a distal end surface of the syringe enclosure before and during the injection event. The Adamis

NDA Product includes a distal end of the needle extending beyond a distal end surface of the syringe enclosure before and during the injection event.

108. Claim 1 of the ‘806 Patent recites a proximal end of the syringe enclosure including a first stop surface and a second stop surface. The Adamis NDA Product includes a proximal end of the syringe enclosure including a first stop surface (the bottom of spacer 220) and a second stop surface (i.e. the element above flange 210).



109. Claim 1 of the ‘806 Patent recites that the first stop surface is configured to limit distal movement of the piston member when piston member is at the second position within the syringe body. The Adamis NDA Product includes the first stop surface configured to limit distal movement of the piston member when piston member is at the second position within the syringe body.

110. Claim 1 of the ‘806 Patent recites that the second stop surface is configured to engage the flange to limit movement of the prefilled syringe assembly within the syringe enclosure. The Adamis NDA Product includes the second stop surface configured to engage the flange 210 to limit movement of the prefilled syringe assembly within the syringe enclosure.

111. Claim 1 of the ‘806 Patent recites an actuator operably coupled to the piston member, movement of the actuator causing a force to be exerted on a proximal end portion of the piston member. On information and belief, the Adamis NDA Product includes an actuator 222 operably coupled to the piston member, movement of the actuator causing a force to be exerted on a proximal end portion of the piston member.

112. kaleo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product by Adamis prior to the expiration of the ‘806 Patent will constitute infringement of that patent.

113. On information and belief, despite having actual notice, at least as of the filing of this complaint, of the ‘806 Patent, Adamis will continue to prepare to infringe the ‘806 Patent in disregard of kaleo’s rights, making this case exceptional and entitling kaleo to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT VIII
**(Declaratory Judgment of Infringement of the ‘806 Patent
Under 35 U.S.C. § 271(b) and (c))**

114. kaleo incorporates each of the preceding paragraphs as if fully set forth herein.

115. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. An actual case or controversy between kaleo and Adamis exists such that the Court may entertain kaleo’s request for declaratory relief consistent with Article III of the United States Constitution.

117. Adamis has actual knowledge of the ‘806 Patent at least as of the date of filing of this complaint.

118. On information and belief, Adamis will act with knowledge of the ‘806 Patent and without a reasonable basis for believing that Adamis would not be liable for actively inducing and contributing to the infringement of the ‘806 Patent.

119. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product would induce the infringement of the ‘806 Patent.

120. On information and belief, Adamis knows or is willfully blind to the fact that its commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product would actively induce the infringement of the ‘806 Patent.

121. On information and belief, Adamis will encourage another’s infringement of the ‘806 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product, which is covered by the claims of the ‘806 Patent.

122. Adamis’s acts of infringement will be done with knowledge of the ‘806 Patent and with the intent to encourage infringement.

123. On information and belief, Adamis knows or is willfully blind to the fact that the Adamis NDA Product will be especially made or especially adapted for use in an infringement of the ‘806 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

124. The commercial manufacture, use, sale, offer for sale, and/or importation of the Adamis NDA Product will contribute to the infringement of the ‘806 Patent.

125. On information and belief, Adamis knows or is willfully blind to the fact that Adamis’s offer for sale, sale and/or importation of the Adamis NDA Product will contribute to the infringement of the ‘806 Patent.

126. The foregoing actions by Adamis will constitute contributory infringement of the ‘806 Patent.

127. kaleo is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Adamis NDA Product by Adamis will induce and/or contribute to infringement of the ‘806 Patent.

128. Unless Adamis is enjoined from actively inducing and contributing to the infringement of the ‘806 Patent, kaleo will suffer irreparable injury for which damages are not an adequate remedy.

129. On information and belief, despite having actual notice of the ‘806 Patent, Adamis will prepare to actively induce and/or contribute to infringement of the ‘806 Patent in disregard of kaleo’s rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

(a) That judgment be entered that Adamis has infringed the ‘022 Patent, the ‘792 Patent and the ‘806 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212854 to the FDA, and that the commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product prior to the expiration of the ‘022, ‘792 and ‘806 Patents would constitute infringement of said patents;

(b) That the Court enter an Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval by the FDA of the Adamis NDA Product be a date which is not earlier than the date of the expiration of the Patents-in-Suit;

(c) That a declaration be issued under 28 U.S.C. § 2201 that if Adamis engages in the commercial manufacture, use, offer for sale, sale and/or importation of the Adamis NDA Product

prior to the expiration of the ‘022 Patent, the ‘792 Patent and the ‘806 Patent, that will constitute infringement of those patents;

(d) That an injunction be issued under 35 U.S.C. § 283 permanently enjoining Adamis, Adamis’s officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Adamis or acting on Adamis’s behalf, from engaging in the commercial manufacture, use, offer to sale or sale within the United States, or importation into the United States, of any product covered by or the use of which is covered by the ‘022 Patent, the ‘792 Patent or the ‘806 Patent, including but not limited to the Adamis NDA Product, prior to the expiration date of such patent, including any extensions or exclusivities;

(e) That damages be awarded to kaleo under 35 U.S.C. §§ 271(a), (b), (c) and/or 35 U.S.C. § 284 for any commercial activities infringing the ‘022 Patent, the ‘792 Patent or the ‘806 Patent;

(f) Declaring that this is an exceptional case under 35 U.S.C. § 285 and that kaleo be awarded reasonable attorneys’ fees and costs; and

(g) That this Court award such other and further relief as it may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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